UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,131	08/27/2003	Anatole Klyosov	13192-116DIV	4786

26486 7590 10/04/2004

PERKINS, SMITH & COHEN LLP
ONE BEACON STREET
30TH FLOOR
BOSTON, MA 02108

EXAMINER	
MCINTOSH III, TRAVISS C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,131	KLYOSOV ET AL.	
	Examiner	Art Unit	
	Traviss C McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 and 36-39 of copending Application No. 10/108,237. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating cancer in a subject comprising administering a galactomannan and a chemotherapeutic agent. It is noted that the instant application is limited to parenteral administration, however, the '237 is not limited to any specific mode of administration, and thus parenteral administration is encompassed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

Claim 5 is objected to because of the following informalities: the claim depends from a claim which is not present (i.e., claim 23). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating cancer with a formulation comprising galactomannan and either 5-FU or adriamycin, does not reasonably provide enablement for treating cancer comprising using a composition comprising galactomannan and any chemotherapeutic agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without undue experimentation.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in ***In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)***. A conclusion of lack of enablement means that, based on the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification,

at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

These factors include:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims - The nature of the invention

The claims are drawn to methods of treating cancer by administering formulations comprising galactomannan and any chemotherapeutic agent. Dependent claims limit the chemotherapeutic agent and the galactose to mannose ratio in the galactomannan.

The state of the prior art

Galactomannan is known in the art to be a polysaccharide which is isolated from various sources. Chemotherapeutic agents are known in the art to be divers in structure and function. The outcome of cancer chemotherapy varies widely in different tumor types and is unpredictable for any individual patient. Results of therapy may vary from complete destruction of the tumor to its continued growth at an unchanged or accelerated rate. The response of any particular tumor to one or a combination of chemotherapeutic agents depends on many biological factors. These factors include the site of the tumor, the stage of tumor development at which therapy has been initiated, the genetic makeup of the tumor cells, and the degree to which the tumor is supplied by local blood vessels, or vascularized. Other, as yet unknown, variables

probably also contribute to the widely differing responses of tumors to chemotherapy and the resulting outcome of treatment in individual patients. (see 6,751,290)

The level of predictability in the art

The examiner acknowledges the probability and predictability that a formulation comprising adriamycin and/or 5-FU can be used effectively in cancer treatment, however the art is silent with regard to the predictability of effectively treating cancer using compositions comprising galactomannan and any other chemotherapeutic agents.

The amount of direction provided by the inventor

The instant specification is not seen to provide adequate guidance which would allow the skilled artisan to extrapolate from the disclosure and examples provided to use the claimed method commensurate in the scope with the instant claims. There is a lack of data and examples which adequately represent the scope of claim as written. The examiner notes, there has not been provided sufficient instruction or sufficient methodological procedures to support the alleged efficacy instantly asserted.

The existence of working examples

The working examples set forth in the instant specification are directed to the use of a combination of galactomannan and either 5-FU or adriamycin. There has not been provided sufficient evidence which would warrant the skilled artisan in oncology, nor a skilled formulation chemist, to accept the data and information provided in the working examples as correlative proof that cancer can be effectively treated using a composition comprising galactomannan and any other chemotherapeutic agent.

The quantity of experimentation needed to make and use the invention based on the content of the disclosure

Indeed, in view of the information set forth supra, the instant disclosure is not seen to be sufficient to enable for making and using a combination of galactomannan and any chemotherapeutic agent without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite wherein the claim is drawn to a method of treating cancer by administering a composition, but the claim is silent as to whom the composition is administered. Adding to whom the composition is to be administered would be seen to obviate the instant rejection.

Claims 2 and 3 recite the limitation "the therapeutic agent" in the second lines of the claims. There is insufficient antecedent basis for this limitation in the claim, as "the therapeutic agent" has not been previously set forth. Changing the claims to read "the chemotherapeutic agent" would be seen to obviate the instant rejection.

Claim 3 is improperly dependent, as the claim depends from claim 2, which limits the therapeutic agent to adriamycin. Claim 3 intends to limit the therapeutic agent to 5-FU, thus, it is

unclear how the therapeutic agent can be limited to adriamycin, and then adriamycin limited to 5-FU. Changing the claim to depend from claim 1 would be seen to obviate the instant rejection.

Claims 4 and 5 are indefinite as they intend to limit the galactomannan to one which is isolated from various plants. The recitation in a dependent claim of the source of an active agent to be used in a method from which said claim depends, wherein the "source of the active agent" does not result in a patentably distinguishable methodological and manipulative difference in how said active agent's source impacts the method from which it depends, renders the claim(s) in which it occurs and which depend therefrom indefinite for failing to distinctly articulate how such a recitation further limits the method from which said dependent claim(s) applicant regards as the invention.

All claims which depend from an indefinite claim are also indefinite. ***Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. "Synthesis and Cytotoxic Activity of Oxidized Galactomannan/ADR Conjugate", J.M.S. Pure Applied Chemistry, 1997, A34(6), pp. 975-989.; US 5,118,673; US 5,834,442; US 5,861,142; US 5,773,425; US 5,786,342. However, none of these references teach or fairly suggest the use a composition comprising a mixture of a galactomannan and a chemotherapeutic agent for treating cancer.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh
September 30, 2004

James O. Wilson
Supervisory Patent Examiner
Art Unit 1623